UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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JEANNE TANSEY,

Plaintiff,

-against-

COCHLEAR LIMITED, an Australian public company, and COCHLEAR AMERICAS CORPORATION, a Delaware corporation,

Defendants.

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OPINION AND ORDER
13-CV-4628 (SJF)

FEUERSTEIN, District Judge:

Defendants Cochlear Americas Corporation ("CAM") and Cochlear Limited ("CLTD") have filed motions to dismiss Jeanne Tansey's ("plaintiff") complaint pursuant to Federal Rule of Civil Procedure ("FRCP") 12(b)(6). CLTD also moves to dismiss pursuant to FRCP 12(b)(2). For the following reasons, CLTD's motion to dismiss for lack of personal jurisdiction is **GRANTED**. CAM's motion to dismiss for failure to state a claim is **GRANTED** in part and **DENIED** in part.

I. Background

Plaintiff is a 36 year old citizen of New York who resides in Suffolk County. Compl. ¶ 11. Defendant CLTD is an Australian public company with its principal place of business in New South Wales, Australia. *Id.* at ¶ 12. Defendant CAM is a Delaware corporation with its principal place of business in Centennial, Colorado and is a wholly owned subsidiary of CLTD. *Id.* at ¶ 13. At all relevant times, defendants, individually and collectively, were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, obtaining regulatory approval for and introducing into interstate commerce throughout the United States,

including New York, either directly or indirectly, numerous cochlear implant medical devices. *Id.* at ¶ 14.

On or about September 14, 2011, the Australian government issued an urgent medical device recall and hazard alert in connection with the unimplanted Cochlear Nucleus CI500 range of implant devices, including the Cochlear Nucleus CI512 ("CI512"), after a recent increase in the number of failures of CI512 implants. *Id.* at ¶¶ 25, 27. On or about October 3, 2011, the Food and Drug Administration ("FDA") issued a Class 2 recall for unimplanted CI512 implants based on a possibility that the devices could shut down and cease to function. *Id.* at ¶¶ 29, 31. On or about December 16, 2011, CLTD publicly issued a letter about the voluntary recall stating that the results of its investigation showed "a loss of heremeticity from unexpected variations in the brazing process during manufacturing. Brazing is the process that joins the feed through a titanium chassis. Variations in the brazing process have resulted in a limited number of implants being more susceptible to developing microcracks in the braze joint during subsequent manufacturing steps." *Id.* at ¶ 33.

According to the complaint, a Cochlear CI512 device was uneventfully implanted in plaintiff's left ear in September 2010 at Long Island Jewish Medical Center in Lakeville, New York. Almost immediately thereafter, plaintiff began to complain to her doctors about experiencing intermittent failure of the device. *Id.* at ¶ 39. Plaintiff was examined by a CAM technician in April 2011, who failed to identify any problem. *Id.* at ¶ 40. Plaintiff continued to complain about her device's intermittent failures until November 11, 2011 when, during an examination, CAM's technician concluded that plaintiff's CI512 device was experiencing a hermeticity failure as per the recall, requiring immediate removal. *Id.* at ¶¶ 41-42. In an attempt

to preserve some of her hearing ability, plaintiff required replacement surgery, which resulted in debilitating injuries and the inability to address profound deafness in her right ear. *Id.* at ¶ 1.

Plaintiff's complaint alleges eight (8) separate claims: (1) strict products liability-manufacturing defect; (2) strict products liability-design defect; (3) strict products liability-failure to inspect; (4) strict products liability-failure to test; and (5) four (4) negligence claims. *Id.* at ¶¶ 110-158.

II. Discussion

A. Legal Standard for FRCP 12(b)(2) Motions

Federal Rule of Civil Procedure 12(b)(2) "permits a defendant to challenge a court's personal jurisdiction over it prior to the filing of an answer or the commencement of discovery." *A.W.L.I. Group, Inc. v. Amber Freight Shipping Lines*, 828 F. Supp. 2d 557, 562 (E.D.N.Y. 2011). In considering a motion to dismiss for lack of personal jurisdiction, a court may rely on materials beyond the pleadings. *Phillips v. Reed Group, Ltd.*, 955 F. Supp. 2d 201, 225 (S.D.N.Y. 2013) (when considering a 12(b)(2) motion, "the Court may also rely on submitted affidavits and other supporting materials submitted in relation to the motion"). "When responding to a Rule 12(b)(2) motion to dismiss for lack of personal jurisdiction, the plaintiff bears the burden of establishing that the court has jurisdiction over the defendant." *Bank Brussels Lambert v. Fiddler Gonzalez & Rodriguez,* 171 F.3d 779, 784 (2d Cir. 1999). Where a court opts to determine the jurisdictional issue without an evidentiary hearing or discovery, a plaintiff need "make only a prima facie showing of jurisdiction through its own affidavits and supporting materials." *Marine Midland Bank, N.A. v. Miller,* 664 F.2d 899, 904 (2d Cir. 1981). "The pleadings and affidavits are construed in the light most favorable to the plaintiff, and all

doubts are resolved in its favor." *Mazloum v. International Commerce Corp.*, 829 F. Supp. 2d 223, 227 (S.D.N.Y. 2011).

To determine whether a federal court has personal jurisdiction over a foreign corporation, it first looks to the law of the state in which the district court sits. *Best Van Lines, Inc. v. Walker*, 490 F.3d 239, 242 (2d Cir. 2007) (citing *Kronisch v. United States,* 150 F.3d 112, 130 (2d Cir. 1998)); *see Arrowsmith v. United Press Intern.*, 320 F.2d 219, 223 (2d Cir. 1963) (holding that personal jurisdiction over a defendant in a "diversity action is determined by the law of the forum in which the court sits."). If a court determines that it can exercise personal jurisdiction over a defendant under the state law, it must then consider "whether asserting jurisdiction under that provision would be compatible with requirements of due process established under the Fourteenth Amendment to the United States Constitution." *Id. See Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945).

B. CLTD's Motion to Dismiss for Lack of Personal Jurisdiction

1. Specific Jurisdiction Pursuant to CPLR § 302(a)[1]

Pursuant to New York's long-arm statute, CPLR 302(a)(3), a court may exercise personal jurisdiction over any non-domiciliary who "commits a tortious act without the state causing injury to person or property within the state . . . if he (i) regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered, in the state, or (ii) expects or should reasonably expect the act to have consequences in the state and derives substantial revenue from interstate or international

[1] Plaintiff does not allege that the Court has general jurisdiction over CLTD and, accordingly, New York's general jurisdiction statute, CPLR § 301, shall not be discussed.

commerce." (McKinney 2013.) "As New York courts have explained, Section 302(a) is a 'single act statute,' and 'proof of one transaction in New York is sufficient to invoke jurisdiction, even though the defendant never enters New York, so long as the defendant's activities here were purposeful and there is a substantial relationship between the transaction and the claim asserted.' " *Phillips*, 955 F. Supp. 2d at 227 (quoting *Kreutter v. McFadden Oil Corp.*, 522 N.E.2d 40, 43 (N.Y. 1988).

Plaintiff contends that this Court has specific jurisdiction over CLTD pursuant to CPLR § 302(a)(3). With respect to the statute's tortious act requirement, plaintiff alleges that CLTD manufactured a defective medical device outside of New York causing injury to plaintiff in New York, where the defective device was implanted in her left ear.

As to sub-prong (i), which requires a showing that the non-domiciliary defendant regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used, consumed or rendered in New York, plaintiff alleges that CLTD derives substantial revenue from New York based on the thousands of implants sent to New York. Based on CLTD's website, its products are so widely used in New York that forty-three (43) separate clinics are present in the state to handle the demand and the thousands of CLTD products sent to New York on a yearly basis.

With respect to § 302(a)(3)(ii), plaintiff contends that CLTD derives substantial revenue from interstate or international commerce. In 2013, CLTD's worldwide revenue, the majority of which was derived from international commerce, was AU$752,721,000, which more than satisfies the substantial revenue requirement. Dec. Silverman, Exh. B at p. 39.

Based on the foregoing allegations and because there is a substantial relationship between the transaction, i.e., CLTD's manufacture and distribution of a defective medical device, and plaintiff's tort claims, plaintiff states a prima facie case of personal jurisdiction over CLTD under CPLR § 302(a)(3)(i) and (ii).

2. Due Process Considerations

If a court determines that it may properly exercise personal jurisdiction over a defendant in accordance with the forum state's law, it must then consider whether the exercise of personal jurisdiction comports with due process. "A court may exercise jurisdiction over only those defendants that have 'minimum contacts' with the forum state 'such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.' " *Phillips*, 955 F. Supp. 2d at 227 (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). "In judging minimum contacts, a court properly focuses on 'the relationship among the defendant, the forum, and the litigation.' " *Calder v. Jones*, 465 U.S. 783, 788 (1984) (quoting *Shaffer v. Heitner*, 433 U.S. 186, 204 (1977)). To establish the minimum contacts necessary to justify "specific" jurisdiction, the claim must arise out of or relate to the defendant's contacts with the forum state, *Helicopteros Nacionales de Columbia, S.A. v. Hall*, 466 U.S. 408, 414 (1984), such that defendant "purposefully availed" itself of doing business and could foresee being "haled into court" in the state. *World-Wide Volkswagon Corp. v. Woodson*, 444 U.S. 408, 414 (1980).

CLTD argues that its sale of a product to CAM, its Colorado-based affiliate, who happened to ship the device to a hospital in New York, which ultimately implanted the device into a local resident, is insufficient to support a finding that CLTD "purposely availed" itself of New York's laws.

CLTD is an Australian public company whose principal place of business is in New South Wales, Australia. Compl. ¶ 12. CLTD products are sold throughout the United States and in over 100 countries. Sec. Dec. York ¶ 2. CLTD has no commercial agents located in New York. Although two (2) of its researchers work from their homes in New York, neither has any connection or role with regard to the sale of CLTD products and neither researcher was involved in the manufacture, sale, distribution or marketing of the CI512 device which is the subject of this lawsuit. Dec. York at ¶ 7. CLTD has no significant connections to New York and does not manufacture, sell or distribute its products in New York. *Id.* at ¶ 10. Rather, CLTD products are sold and distributed exclusively by CAM, which purchases products from CLTD for independent distribution throughout the United States. *Id.* CLTD is not registered to do business in New York and does not have a New York mailing address, telephone number, office, manufacturing plant, bank account, no real or tangible property and does not pay income taxes in New York. *Id.* at ¶¶ 8, 10, 11. The foregoing facts, and the lack of any contact with New York weigh against the exercise of personal jurisdiction over CLTD.

Plaintiff argues that CLTD's relationship with its wholly owned subsidiary, defendant CAM, establishes minimum contacts that comport with due process and that CAM's actions should be imputed to CLTD.

"The presence of a wholly owned subsidiary in New York is normally an insufficient basis for establishing jurisdiction." *Chichelo v. Hoffman-La Roche Inc.*, No. 97 Civ. 4591, 1997 WL 654637, at *2 (S.D.N.Y. Oct. 21,1997). *See Bialek v. Racal-Milgo, Inc.*, 545 F. Supp. 25, 31-32 (S.D.N.Y. 1982) ("It is well settled that a corporation may not be subjected to the jurisdiction of the New York courts merely because a wholly-owned subsidiary of the corporation

is doing business in New York in the traditional sense.") (citing *Bellomo v. Penn. Life Co.*, 488 F. Supp. 744, 745 (S.D.N.Y. 1982)); *see also Daimler A.G. v. Bauman*, 134 S. Ct. 746, 759-60 (2014) (reversing the Ninth's Circuit adoption of a "less rigorous [agency] test" for imputing a subsidiary's jurisdictional contacts to a parent and holding that it "appears to subject foreign corporations to general jurisdiction whenever they have an in-state subsidiary or affiliate, an outcome that would sweep beyond even the 'sprawling view of general jurisdiction' we rejected in [*Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2856 (2011)]." Besides improperly subjecting CLTD to New York's jurisdiction, imputing CAM's jurisdictional contacts to CLTD is especially inappropriate where, as here, the subsidiary's place of business is also outside the State, i.e., Colorado. Compl. ¶ 13.

"Only if grounds exist for piercing the corporate veil can the presence of a subsidiary be used as the basis for jurisdiction over a parent company." *Id.* To that end, CLTD submits an affidavit from its Group Financial Controller who swears under penalty of perjury that CLTD and CAM are separate legal entities, which file separate tax returns and prepare separate financial statements. Sec. Dec. York at ¶¶ 3, 4. The companies maintain separate corporate books and records, including separate minutes and separate board resolutions for their respective boards of directors. *Id.* at ¶ 5. CLTD and CAM have no common bank accounts, no common officers and share one common director. *Id.* at ¶¶ 6, 7. CAM employs its own employees and the companies maintain separate and distinct accounting, human resources, information technology, legal and other administrative departments. *Id.* at ¶¶ 8, 10. CAM conducts day-to-day operations independent of CLTD and makes its own decisions regarding where to market CLTD products in the United States. CLTD has never directed CAM to make CLTD products in any particular

state, including New York State, nor has CLTD ever directed CAM to target New York for the sale of its products. *Id.* at ¶ 11. Furthermore, CAM is not authorized to accept service of process or to sign contracts on behalf of CLTD. *Id.* at ¶ 12. Given the foregoing, no grounds exist to impute CAM's presence in the state to CLTD.

With respect to its website, CLTD submits a declaration from the individual in charge of its online activities. According to the sworn declaration, CLTD maintains a website to provide users with general information regarding CLTD products and services. Dec. Narayanan ¶ 3. After a user accesses CLTD's website, a pop-up immediately requests that users select their country; users who select "United States & Canada" are immediately directed to another website maintained by CLTD's affiliate, defendant CAM. *Id.* at ¶¶ 4, 5. In addition, CLTD does not sell products on its website and CLTD employees are not responsible for maintaining and/or updating the content of the CAM website. *Id.* at ¶¶ 6, 7. Accordingly, CLTD's website is deemed "passive" and cannot provide a basis for personal jurisdiction over CLTD. *See Royalty Network, Inc. v. Dishant.com, LLC*, 638 F. Supp. 2d 410, 418 (S.D.N.Y. 2009) (noting the "spectrum" of website interactivity and holding that "[a]t one end are "passive" websites—i.e., those that merely make information available to viewers. "Such websites have 'been analogized to an advertisement in a nationally-available magazine or newspaper, and do[] not without more justify the exercise of jurisdiction over the defendant.' ") (quoting *Citigroup Inc. v. City Holding Co.*, 97 F. Supp. 2d 549, 565 (S.D.N.Y. 2009)).

For all of the foregoing reasons, plaintiff has not alleged a prima facie case for personal jurisdiction over CLTD which would not offend traditional notions of fair play and substantial justice. Given CLTD's lack of any contacts with New York, there is no evidence that the

company purposefully availed itself of doing business in New York or that it was "at home" here. Thus, the due process clause prohibits the exercise of personal jurisdiction over CLTD and, accordingly, CLTD's motion to dismiss is granted and it is dismissed from this case.

Plaintiff requests that in the event CLTD's motion is granted, it be permitted to engage in jurisdictional discovery because discovery "is particularly appropriate where available information suggests . . . jurisdiction over a parent entity through the acts of the subsidiary." Mem. in Opp. p. 25. As discussed above, a wholly owned subsidiary's relationship with its parent corporation is insufficient to establish minimum contacts, unless reasons exist to pierce the corporate veil. Plaintiff does not identify the available information and based on the sworn affidavit from CLTD's chief financial officer, discussed *supra*, there do not appear to be such grounds here. Consequently, plaintiff's request for jurisdictional discovery is denied.

C. Legal Standard for FRCP 12(b)(6) Motions

When considering a motion to dismiss a complaint for failure to state a claim, the court must assume as true all allegations contained in the complaint. *Chance v. Armstrong*, 143 F.3d 698, 701 (2d Cir. 1998). However, it is "well settled that conclusory allegations merely stating general legal conclusions necessary to prevail on the merits of a claim, unsupported by factual averments will not be accepted as true." *ECOR Solutions, Inc. v. Malcolm Pirnie, Inc.*, No. 02 Civ. 1103, 2005 WL 1843253, at *3 (N.D.N.Y. July 29, 2005). The Supreme Court has held that a "plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). On FRCP 12(b)(6) motions, the court must assess the legal feasibility of the complaint and whether a plaintiff has pled claims for

which he or she is entitled to discovery. *Sims v. Artuz*, 230 F.3d 14, 20 (2d Cir. 2000); *Chance*, 143 F.3d at 701.

In *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009), the Supreme Court held that courts should entertain a motion to dismiss by following a two-pronged approach:

> [A] court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

The Federal Rules of Civil Procedure require a "short plain statement of the claim showing that the pleader is entitled to relief." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007) (quoting Fed. R. Civ. P. 8(a)(2)). Rule 8(a)(2) requires that a pleading set forth facts that the pleader is entitled to relief and provide a defendant with fair notice. *Leatherman v. Tarrant County Narcotics Intelligence and Coordination Unit,* 507 U.S. 163, 168 (1993) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

D. Defendant's 12(b)(6) Motion[2]

1. Preemption under the MDA

Defendant CAM argues that plaintiff fails to state a claim because her New York tort law claims are expressly preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA") and, to the extent the claims are not preempted, the

[2] Defendant CLTD incorporates by reference CAM's motion to dismiss for failure to state a claim. DE 25-1 at p. 2. Having held, however, that the Court does not have personal jurisdiction over CLTD, the motion is limited to CAM because CLTD is dismissed from this case.

allegations do not comply with the pleading standards under *Twombly* and *Iqbal*. Plaintiff contends that her state law claims are not preempted because her claims "parallel" the federal requirements.

The MDA gives the Food and Drug Administration ("FDA") "authority over medical devices and authorizes the FDA to issue implementing regulations." *Richman v. W.L. Gore & Assoc., Inc.*, 881 F. Supp. 895, 899 (S.D.N.Y. 1995). The MDA requires medical device manufacturers to register each device with the FDA prior to beginning manufacture. *Id.* at 900 (citing 21 U.S.C. § 360c). After a device is registered, the FDA "classifies each device according to the level of regulatory control necessary to provide for the device's safety and effectiveness." *Id.*

Medical devices are classified by three (3) categories based on the risk they pose to the public. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). "[D]evices that either 'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' are designated Class III." *Id.* (quoting 21 U.S.C. § 360c(a)(1)(A). Class III devices "are the most heavily regulated and must pass premarket approval." *Richman*, 881 F. Supp. at 900. The CI512 is a Class III medical device.

The MDA's preemption language with respect to medical devices is codified at 21 U.S.C. § 360k(a):

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The Supreme Court has held that § 360k does not preempt state-law claims that "parallel" federal requirements. *Lohr*, 518 U.S. at 495. The Court reasoned that in enacting § 360k, Congress "was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions." *Id.* at 489.

With respect to claims that a manufacturer made fraudulent representations to the FDA to obtain approval for a Class III device, however, such claims "are inherently federal in nature" given the relationship between the FDA and the manufacturer, which "originates from, is governed by, and terminates according to federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001). Accordingly, state-law "fraud-on-the-agency" claims conflict with federal law and are impliedly preempted. *Id.* at 348.

Most recently, the Court considered whether § 360k "bars common-law claims challenging the safety and effectiveness of a medical device given premarket ("PMA") approval by the Food and Drug Administration." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). *Riegel* involved an FDA approved balloon catheter that ruptured in the plaintiff's coronary artery after the doctor inflated the device beyond its rated burst pressure. *Id.* at 320. The complaint alleged that the catheter was designed, labeled and manufactured in violation of New York's common law. *Id.* The catheter is a Class III device that received PMA from the FDA. *Id.* The district court dismissed plaintiff's claims alleging strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing and sale of the catheter as preempted by the MDA. *Id.* The Second Circuit Court of Appeals affirmed the dismissals and concluded that the catheter was "clearly subject to the federal device-specific requirement of adhering to the standards contained in its individual, federally approved"

premarket approval application. *Riegel v. Medtronic Inc.*, 451 F.3d 104, 118 (2d Cir. 2006). The claims were preempted because they "would, if successful, impose state requirements that differed from, or added to, the PMA-approved standards." *Id.* at 121.

To determine whether the state-law claims were preempted by § 360k, the Court applied a two-part test: (1) whether the federal government has established "requirements" applicable to the specific device; and, if so, (2) whether the state common law claims are based upon state-law requirements that are "different from, or in addition to," the federal requirements and relate to safety and effectiveness. *Riegel*, 522 U.S. at 321-22 (quoting § 360k(a)(1) and (2)).

With respect to the first inquiry, the Court held that PMA approval imposes "requirements" under the MDA that are specific to individual medical devices and which are focused on safety. *Id.* at 322-23. Next, the Court considered whether the common-law claims relied upon New York law which applied to the device at issue and which was different from, or in addition to, federal requirements "and that 'relates to the safety or effectiveness of the device or to any other matter included in the requirement applicable to the device.' " *Id.* at 323 (quoting § 360k(a)(2)). The Court affirmed the Second Circuit's dismissal of the tort claims and concluded that "common law causes of action for negligence and strict liability do impose 'requirement[s]' and would be preempted by federal requirements specific to a medical device."[3] *Id.* at 323-24.

The Court also held, however, that § 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a

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[3] The *Riegel* plaintiffs failed to raise the "parallel" regulation argument in both the district and circuit courts and consequently, the Supreme Court declined to address their argument in the first instance. *Riegel*, 552 U.S. at 330.

case "parallel," rather than add to, federal requirements." 552 U.S. at 330. Since then, courts "interpreting *Riegel* have held that state-law claims "parallel" federal regulations, and thus are not preempted, only in a narrow set of circumstances: where the defendant allegedly violated FDA regulations, but the violation is not itself the basis of the claim." *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 402 (S.D.N.Y. 2013) (citing cases). *See Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) ("The Supreme Court thus has made clear that section 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law."); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 155 (S.D.N.Y. 2011) (holding that plaintiff's state law claim was not preempted where the complaint alleged that a device was manufactured with residuals exceeding that allowed by the device's criteria). "For example, a plaintiff's state tort claim would be pre-empted if it alleged the device, as approved by the FDA, was unreasonably dangerous. . . . But a plaintiff could bring a state tort claim alleging a manufacturer's device, as produced, was adulterated and therefore did not conform to that device's specific FDA premarket approval requirements." *Gale v. Smith & Nephew, Inc.*, No. 12 Civ. 3614, 2013 WL 563403, at *3 (S.D.N.Y. Feb. 13, 2013) (citation omitted).

Thus, to determine whether a claim is preempted by the MDA: (1) a court must find that the FDA imposes federal requirements on the particular medical device; (2) if federal requirements apply, the court must determine whether plaintiff's claims are based on a state law that " 'relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device' "; and (3) if the state law imposes requirements, whether they are different from, or in addition to, the federal requirements. *Horowitz v. Stryker Corp.*,

613 F. Supp. 2d 271, 279 (E.D.N.Y. 2009) (quoting *Riegel*, 552 U.S. at 323). State law claims are preempted if they impose requirements that differ from, or are in addition to, the federal regulations. *Id.*

2. Plaintiff's Complaint

"To avoid preemption and satisfy the *Twombly* and *Iqbal* pleading standards, plaintiffs suing with regard to a PMA-approved device cannot simply make the conclusory allegation that defendant's conduct violated FDA regulations." *Simon*, 990 F. Supp. 2d at 403. "Rather, to state a parallel claim plaintiff must 'set forth facts pointing to specific [premarket approval] requirements that have been violated,' and link those violations to his injuries." *Gale*, 989 F. Supp. 2d at 249 (quoting *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011)).

As to the first inquiry, "premarket approval . . . imposes "requirements" under the MDA which is specific to particular devices and the FDA requires a device that has received PMA to be manufactured "with almost no deviations from the specifications in its approval application." *Riegel*, 552 U.S. at 322-23. The FDA also requires that any changes to either the device's specifications or conditions of the original PMA be approved. 21 U.S.C. § 360e(d)(6)(A)(i). There is no dispute that the CI512 went through the PMA process and received FDA approval. Consequently, the FDA imposes specific federal requirements on the device.

As for the second inquiry, plaintiff's claims for strict liability and negligence concern violations that relate to the safety or effectiveness of the device or to other matter included in the requirements that apply to the device, which subjects the claims to possible preemption. *Riegel*

v. Medtronic, Inc., 451 F.3d 104, 106 (2d Cir. 2006) (holding that state tort claims which impose "liability as to a PMA-approved medical device, notwithstanding that device's adherence to the standards upon which it obtained premarket approval from the FDA, are preempted").

With respect to the third inquiry, whether the common law claims differ from, add to or parallel the requirements specific to the device, plaintiff alleges that her claims do not challenge the FDA's approval of the design, manufacturing process or labeling of the device. Compl. ¶ 8. Rather, according to the complaint, plaintiff's claims parallel the federal requirements because she seeks to hold defendant responsible for its failure to comply with, and for deviations from, the specifications and requirements of the PMA approval specifications. *Id.*

a. Manufacturing Defect Claims

Plaintiff's first claim alleges that defendant is strictly liable for the manufacturing defects in her CI512 device. *Id.* at ¶¶ 110-114. Plaintiff's sixth claim alleges that defendant is liable for the defects under common-law negligence. *Id.* at ¶¶ 143-152. "To plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (quoting *Caprara v. Chrysler Corp.*, 417 N.E.2d 545, 552-53 (N.Y. 1981)). " '[I]n strict products liability cases involving manufacturing defects, the harm arises from the product's failure to perform in the intended manner due to some flaw in the fabrication process.' " *Preston v. Peter Luger Enterprises, Inc.*, 858 N.Y.S.2d 828, 831 (N.Y. App. Div. 2008) (quoting *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 735 n.3 (N.Y. 1995)). "In

order to succeed on such a claim, a plaintiff must establish that the product was not built to specifications or that the product, 'as constructed, deviated from any such specifications or design.' " *McArdle v. Navistar Int'l Corp.*, 742 N.Y.S.2d 146, 148 (N.Y. App. Div. 2002) (quoting *Searle v. Suburban Propane Div. of Quantum Chem. Corp.*, 700 N.Y.S.2d 588, 592 (N.Y. App. Div. 2000)).

Plaintiff's complaint alleges that her CI512 implant, and those implants subject to the October 2011 recall, deviated in a material way from defendant's approved product manufacturing specifications, PMA manufacturing specifications, current good manufacturing practices ("CGMP") and/or other applicable federal law, causing an unreasonably dangerous risk of hermeticity and related device failures which required plaintiff to under go additional medical treatment to remove and replace the CI512 implant. Compl. ¶ 112. Plaintiff's complaint cites to FDA requirement 21 U.S.C. § 351(h), which provides, in part, that a device "shall be deemed to be adulterated" where "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements" in GCMP regulations. *Id.* at ¶ 77. The CGMP, 21 C.F.R. § 820.70(a), generally applicable to a variety of medical devices, requires each manufacturer to: "develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications." *Id.* at ¶ 76. CGMP 21 C.F.R. § 820.70(h) provides: "Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material." *Id.* at ¶ 84. Plaintiff also alleges that as a direct and proximate result of her use of the device as manufactured by defendant, she suffered serious physical harm, damages, economic loss and will continue to

suffer such harm. *Id.* at ¶ 113.

Defendant contends that plaintiff's claims are preempted because they depend on a finding that the CI512 should have been manufactured in a manner different from that approved by the FDA through the PMA approval process. Mem. in Supp. p. 12. CAM argues that "claims challenging the sufficiency of a PMA-approved device's manufacturing process are precisely the type of claim found to be preempted in *Riegel*." *Id.* Defendant also argues that negligent manufacture is one of the many state law tort claims preempted by the federal regulatory scheme that governs the testing and approval process. *Id.*

Defendant, however, fails to point out how plaintiff's manufacturing defect claims differ from, or add to, any FDA requirements with respect to the CI512. Furthermore, the argument that the claims are preempted because they require different manufacturing from that approved by the FDA misstates plaintiff's claims. The complaint alleges that defendant deviated from the FDA approved plan and specifications and that the deviation, i.e., the breach of hermeticity, was the cause of plaintiff's injury. "Allegations regarding adulterations in particular can sufficiently state a claim where the violation of CGMPs also indicate a deviation from PMA requirements." *Franzese v. St. Jude Med. Center, Inc.*, No. 13 Civ. 3202, 2014 WL 2863087, at *5 (E.D.N.Y. June 23, 2014). Accordingly, plaintiff's strict liability and negligent manufacturing claims parallel the federal requirements and are not preempted under § 360k. Additionally, the allegations comply with the standards in *Twombly* and *Iqbal*. Defendant's motion to dismiss plaintiff's manufacturing defect claims is, therefore, denied.

b. Design Defect Claims

Plaintiff's second claim alleges that defendant is "the designer[] and/or manufacturer[] and/or distributor[] and/or seller[] and/or supplier[]" of plaintiff's CI512 implant and of those implants subject to the October 2011 recall." Compl. ¶¶ 116. The complaint also alleges that plaintiff's implant and those subject to the October 2011 recall "were defective in their design, when they left the hands of Defendant[] in that the design of Plaintiff's CI512 implant . . . deviated in a material way from defendant's approved product design specifications, the PMA design specifications, Defendant's approved design performance standards, CGMP, and/or other applicable federal law and federal regulations applicable to the design" of plaintiff's implant. *Id.* at ¶ 117.

Under New York law, "a design defect may be actionable under a strict products liability theory if the product is not reasonably safe." *Denny*, 662 N.E.2d at 735. "[T]he New York standard for determining the existence of a design defect has required an assessment of whether 'if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner.' " *Id.* (quoting *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207 (N.Y. 1983)). "To state a claim for strict products liability under a design defect theory, a plaintiff must allege that '(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury.' " *Simon*, 990 F. Supp. 2d at 403 (quoting *Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001).

"Strict products liability for design defect . . . differs from a cause of action for a

negligently designed product in that the plaintiff is not required to prove that the manufacturer acted unreasonably in designing the product." *Voss*, 450 N.E.2d at 207. Rather, the focus shifts "from the conduct of the manufacturer to whether the product, as designed, was not reasonably safe." *Id.*

Plaintiff's design defects claims are preempted under § 360k because such claims challenge the PMA approval of the design for the CI512. For plaintiff to prevail on a design defect claim, she must demonstrate the existence of a feasible and safer alternative design than that espoused by the FDA, which is at odds with its approval of the design and adds to the federal requirements. *See Bertini v. Smith & Nephew, Inc.*, No. 13 Civ. 79, 2014 WL 1028950, at *6 (E.D.N.Y. Mar. 17, 2014) ("[A]n action based on state law that would require a manufacturer to design a device, which has already received PMA approval, in a manner that is safer than what the FDA requires would impose additional state safety requirements on the device, and therefore this claim would be preempted under § 360k."); *Simon*, 990 F. Supp. 2d at 405 (holding that design defect claims regarding a PMA-approved device are squarely preempted by the MDA). In addition, plaintiff would have to allege and prove that the device as designed posed a substantial likelihood of harm, which also directly challenges PMA approval.

Furthermore, plaintiff's contention that defendant deviated from the approved design and the deviation resulted in the breach of hermeticity (compl. ¶ 117) is unpersuasive. The complaint alleges that the "loss of hermeticity . . . resulted from unintended variations in the brazing process that occurred during the Defendant['s] manufacture" of the devices. Compl.¶ 63. These "unintended variations in the brazing process during the manufacture of the CI512 implants . . . resulted in the CI512 implants being dangerously susceptible to developing Microcracks in its

braze joint during subsequent manufacturing processes." *Id.* at ¶ 65. The complaint also alleges: "Microcracks developed in the braze joint of the CI512 implants . . . during the manufacturing process." *Id.* at ¶ 66. The complaint's allegations, accepted as true for the purposes of this motion, establish that the breach of hermeticity resulted from the manufacturing processes and not because defendant allegedly deviated from the PMA approved design. Accordingly, for the foregoing reasons, defendant's motion to dismiss plaintiff's design defect claim is granted.

c. Strict Liability Failure to Inspect Claim

Plaintiff's third claim alleges that plaintiff's device and those subject to the October 2011 recall, were defective in their design and/or manufacture, construction or composition when they left the hands of defendant because they deviated in a material way from defendant's approved product specifications, the PMA product specifications, defendant's approved product performance standards, CGMP and/or other applicable federal law applicable to the CI512 implant, creating an unreasonably dangerous risk of hermeticity failure and related medical device failure. *Id.* at ¶122. This conduct rendered plaintiff's implant "more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner." *Id.* The risks and failures described above were caused by defendant's failure to inspect the materials, components and completed projects concerning the implant prior, during and subsequent to the manufacturing process. *Id.* at ¶ 23. As a direct result of defendant's failure to properly and adequately inspect, consistent with the PMA and federal requirements, the materials, components and completed products that comprised plaintiff's medical device, the devices contained defects which rendered them dangerous and unsuitable for transplant. Compl. ¶ 124. As a direct and proximate result of plaintiff's use of the implant and defendant's failure to

comply, plaintiff suffered serious physical injury, harm, damages and economic loss. *Id.* at ¶ 125.

To satisfy the pleading standards established by *Iqbal* and *Twombly*, plaintiff 'cannot simply incant the magic words '[defendants] violated FDA regulations' in order to avoid preemption.' " *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 249 (S.D.N.Y. 2013) (quoting *In re Medtronic Inc.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)). "Rather, to state a parallel claim plaintiff must 'set forth facts pointing to specific [premarket approval] requirements that have been violated,' and link those violations to his injuries. *Id.* (quoting *Wolicki–Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011)).

Plaintiff's complaint fails to cite to any New York case law in support of her failure to inspect claim, nor does she point to federal device specific requirements which defendant allegedly breached and which her state law claim allegedly parallels. Consequently, plaintiff states neither a parallel state law claim nor a claim under *Twombly* and *Iqbal*. Accordingly, defendant's motion to dismiss for failure to state a claim is granted.

d. Negligent Failure to Warn Claim

Plaintiff's fifth claim is labeled "negligence," and seemingly alleges a product liability failure to warn claim. Compl. ¶ 135. The complaint states that defendant owed plaintiff a duty of care which it violated by failing to report known risks associated with the use of the implant. *Id.* Defendant negligently failed to timely and adequately warn health care professionals and the public, including plaintiff, her treating physicians, surgeons and its own technicians of the true risks associated with plaintiff's CI512 implant, including its propensity to fail and the reason for the failure. *Id.* at ¶ 136. Defendant failed to comply with its duty under federal law and breached

its duty to use reasonable care under New York State law. *Id.* at ¶ 137. Defendant also failed to timely and reasonably warn of material facts regarding the safety and efficacy of plaintiff's device and, as a direct and proximate cause of defendant's conduct, plaintiff suffered or will suffer serious and permanent non-economic and economic injuries. *Id.* at ¶ 140.

To prevail on this claim, plaintiff must " 'demonstrate that (1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm.' " *Franzese*, 2014 WL 2863087, at *6 (quoting *Burkett v. Smith & Nephew Gmbh*, No. 12 Civ. 4895, 2014 WL 1315315, at *6 (E.D.N.Y. Mar. 31, 2014)).

According to the complaint, plaintiff's surgery took place sometime in September 2010. Compl. ¶ 39. Approximately one (1) year later, on or about September 14, 2011, the Australian government issued an urgent medical device recall in connection with unimplanted CI512s. *Id.* at ¶ 25. On or about October 3, 2011, the FDA issued a recall for unimplanted devices based on the possibility that the devices could shut down and cease functioning. *Id.* at ¶ 29.

Given the foregoing and the fact that the warning letter was issued more than one (1) year after plaintiff's surgery, plaintiff cannot establish proximate cause because a failure to warn after the fact cannot be the cause of plaintiff's damages. *See Franzese*, 2014 WL 2863087, at *6 (dismissing plaintiff's failure to warn claim for lack of proximate cause where an FDA warning letter regarding plaintiff's medical device was issued nearly three (3) years after plaintiff's surgery); *Gelber*, 788 F. Supp. 2d at 161 (dismissing plaintiff's failure to warn claim and stating: "Plaintiffs fail to explain how defendants could have acted on the findings from these medical studies, when the results of these studies were not presented until 2006, approximately two years

after she received her implant."). Accordingly, defendant's motion is granted as to plaintiff's fifth claim and the claim is dismissed.

e. Negligence Claim

Plaintiff's seventh claim alleges that defendant, its servants, agents and employees, including those technicians conducting an inquiry into the nature and cause of plaintiff's ongoing complaints concerning the performance of plaintiff's CI512 implant after her September 2010 surgery, owed a duty to plaintiff to "possess and exercise the degree of skill and competence expected of an individual engaged in such an occupation or profession." Compl. ¶ 153. Defendant, its servants, agents and employees negligently failed to exercise the degree of care and expertise expected of an individual under the circumstances then and there prevailing given their capacity, educations, training and background by negligently failing to timely determine that explant surgery of plaintiff's device was necessary. *Id.* at ¶154. As a result, plaintiff suffered from hearing loss and pain and suffering during this entire period which resulted in plaintiff suffering a poor outcome and an inability to address a profound deafness in her right ear. *Id.* As a result, defendant is liable to plaintiff for past and future medical expenses, past and future lost wages. *Id.* at ¶ 155.

To prevail on a negligence claim under New York law, a plaintiff must establish that a defendant: (1) owed a duty of care; (2) breached that duty; (3) that the breach was the proximate cause of the plaintiff's injuries; and (4) damages. *Vega v. Fox*, 457 F. Supp. 2d 172, 183 (S.D.N.Y. 2006). Plaintiff's complaint alleges that defendant and its agents owed plaintiff a duty, which was breached by negligently failing to exercise the expected degree of care under the circumstances. Defendant's breach was the cause of plaintiff's damages. Plaintiff's claim

satisfies the pleading standards and defendant's motion to dismiss is denied.

f. Alternative Negligence Claim

Plaintiff's eighth and last claim alleges that defendant, its servants, agents and employees, including those technicians conducting an inquiry into the nature and cause of plaintiff's ongoing complaints concerning the implanted CI512, owed plaintiff a duty to possess and exercise the degree of skill and competence expected of an individual engaged in such an occupation or profession. Compl. ¶ 156. Defendant and its agents negligently failed to exercise the degree of care or expertise required by "negligently and incorrectly concluding that Plaintiff's CI512 was failing consistent with and as encompassed by the October CI512 recall and that Plaintiff's CI512 required immediate explant surgery when in fact the Tansey implant was not suffering from the failings attributable" to the recall and did not require immediate explant surgery thereby exposing plaintiff to unnecessary surgery and damages which flowed directly therefrom. *Id.* at ¶ 157. As a result, defendant is liable to plaintiff for past and future medial expenses, past and future lost wages and past and future pain and suffering damages. *Id.* at ¶ 158.

Federal Rule of Civil Procedure 8(d)(2) provides that a "party may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones." Such pleading in the alternative is permitted at this stage of the case. *See GlaxoSmithKline LLC v. Beede*, No. 13 Civ. 0001, 2014 WL 896724, at *7 (N.D.N.Y. Mar. 6, 2014) (holding that at the motion to dismiss stage, a plaintiff is permitted to pursue alternative remedies). In addition, the complaint does not incorporate the preceding paragraphs into this claim. Moreover, the claim complies with the requirements of *Twombly* and *Iqbal* in that it alleges the elements of a negligence claim in a non-conclusory fashion. Accordingly, defendant's

motion to dismiss plaintiff's eighth claim is denied.

III. Conclusion

For the foregoing reasons, CLTD's motion to dismiss pursuant to FRCP 12(b)(2) for lack of personal jurisdiction is **GRANTED** and CLTD is dismissed from this case. Defendant CAM's motion to dismiss pursuant to FRCP 12(b)(6) is **GRANTED** as to plaintiff's Second, Third, Fourth and Fifth Claims and is **DENIED** as to plaintiff's First, Sixth, Seventh and Eighth claims.

SO ORDERED.

Dated: September 26, 2014
Central Islip, New York

Sandra J. Feuerstein, U.S.D.J.